CHARLES LIFLAND (S.B. #108950)
clifland@omm.com
SABRINA H. STRONG (S.B. #200292)
sstrong@omm.com
O'MELVENY & MYERS LLP
400 South Hope Street
Los Angeles, CA 90071
Tel: (213) 430-6000
Fax: (213) 430-6407

AMY LAURENDEAU (S.B. #198321)
O'MELVENY & MYERS LLP
610 Newport Center Drive, 17th Floor
Newport Beach, CA 92660
Tel: (949) 823-6900
Fax: (949) 823-6994
alaurendeau@omm.com

AMY R. LUCAS (S.B. #264034)
O'MELVENY & MYERS LLP
1999 Avenue of the Stars, 8th Floor
Los Angeles, CA 90067
Tel: (310) 553-6700
Fax: (310) 246-6779
alucas@omm.com

Attorneys for Defendants Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc.

[Additional counsel appear on signature page.]

UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

THE CITY AND COUNTY OF SAN FRANCISCO, et al.,

Plaintiffs,

v.

PURDUE PHARMA L.P., et al.,

Defendants.

Case No. 3:18-cv-07591-CRB

MANUFACTURER DEFENDANTS' NOTICE OF JOINT MOTION AND JOINT MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED COMPLAINT; MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT THEREOF

Date: June 19, 2020
Time: 10:00 a.m.
Dept: Courtroom 6
Judge: Honorable Charles R. Breyer

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that, on June 19, 2020, at 10:00 a.m., or as soon as this matter may be heard thereafter in Courtroom 6, 17th Floor, of the United States District Court, Northern District of California, located at 450 Golden Gate Avenue, San Francisco, California, the Honorable Charles R. Breyer presiding, the Manufacturer Defendants[1] will and hereby do move this Court for an order dismissing the City and County of San Francisco's First Amended Complaint without leave to amend pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6).

This motion is based on this Notice of Motion and Motion to Dismiss, the accompanying Memorandum of Points and Authorities in support thereof, the concurrently filed Request for Judicial Notice and Declaration of Charles C. Lifland, the Proposed Order, any Reply Memorandum, the pleadings and files in this action, and such arguments and authorities as may be presented at or before the hearing.

[1] The Manufacturer Defendants (or "Manufacturers") are Defendants Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a/ Watson Pharmaceuticals, Inc., Allergan Sales, LLC and Allergan USA, Inc., Endo Pharmaceuticals Inc., Endo Health Solutions Inc., Par Pharmaceutical, Inc., and Par Pharmaceutical Companies, Inc., Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc., Mallinckrodt LLC, SpecGx LLC, Noramco, Inc., Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Actavis LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc; Watson Laboratories, Inc.; Warner Chilcott Company LLC; Actavis South Atlantic LLC; Ac-tavis Elizabeth LLC; Actavis Mid Atlantic LLC; Actavis Totowa LLC; Actavis Kadian LLC; Actavis Laboratories UT, Inc. f/k/a Watson Laboratories, Inc.-Salt Lake City; and Actavis Laboratories FL, Inc. f/k/a Watson Laboratories, Inc. Florida.
Some of the Manufacturer Defendants are also "Generic Manufacturers," including Watson Laboratories, Inc.; Warner Chilcott Company, LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc.; Actavis LLC; Actavis South Atlantic LLC; Actavis Elizabeth LLC; Actavis Mid Atlantic LLC; Actavis Totowa LLC; Actavis Kadian LLC; Actavis Laboratories UT, Inc.; Actavis Laboratories FL, Inc.; Par Pharmaceutical, Inc.; Par Pharmaceutical Companies, Inc.; Mallinckrodt LLC; and SpecGx LLC.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

CASES

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

STATUTES

TABLE OF AUTHORITIES
(continued)

Page

RULES

I. SUMMARY OF ARGUMENT

This Motion[1] outlines several manufacturer-specific grounds necessitating dismissal of the FAC.[2] *First*, the marketing enterprise and supply chain enterprise RICO claims fail because the City did not plausibly plead facts establishing causation, as there is no "***direct*** relation" between the City's injuries and Manufacturers' conduct, *Holmes v. Sec. Inv. Prot. Corp.*, 503 U.S. 258, 268 (1992) (emphasis added), and there are "numerous alternative causes that might be the actual source" of the public health crisis, *Canyon Cnty. v. Syngenta Seeds, Inc.*, 519 F.3d 969, 983 (9th Cir. 2008). Equally dispositive is the City's failure to allege *any* predicate act with particularity.

Second, the City's claims under the FAL and the UCL's "fraudulent" prong fail for multiple reasons. California's safe harbor doctrine bars the City's challenge to promotions of opioids consistent with their FDA-approved labels. *See Cel-Tech Commc'ns, Inc. v. L.A. Cellular Tel.*, 20 Cal. 4th 163, 183 (1999). Even if it did not, the challenged statements are not actionable because (1) they were unlikely to deceive reasonable physicians, *Lavie v. Procter & Gamble Co.*, 105 Cal. App. 4th 496, 504, 507-08, 512 (2003); and (2) Manufacturers did not personally participate in or have "unbridled control" over the FAC's challenged third-party statements, *Emery v. Visa Int'l Serv. Ass'n*, 95 Cal. App. 4th 952, 960 (2002), most of which are constitutionally protected speech, *see Bernardo v. Planned Parenthood Fed'n of Am.*, 115 Cal. App. 4th 322, 344-48 (2004).

Third, the City's failure to adequately plead its RICO, FAL, and CLRA claims is fatal to its claim under the UCL's "unlawful" prong because "[w]hen a statutory claim fails, a derivative UCL claim also fails." *Aleksick v. 7-Eleven, Inc.*, 205 Cal. App. 4th 1176, 1185 (2012).

Fourth, the City's claims fail under the UCL's "unfair" prong due to (1) the FAC's inadequate allegations of substantial harm *proximately caused by* Manufacturers' marketing, and (2) their "strong justification" of providing therapeutic relief to pain patients. *See Davis v. HSBC Bank Nev., N.A.*, 691 F.3d 1152, 1170 (9th Cir. 2012).

Fifth, the City's public nuisance claim fails because the FAC does not provide a causal link

[1] Noramco, Inc. ("Noramco") joins this Motion to the extent applicable and reserves all rights and defenses specific to it, as explained in greater detail in the Joint Brief. *See* Joint Br. at n. 1.

[2] Unless otherwise stated, all acronyms are defined in the concurrently-filed Defendants' Notice of Joint Motion and Joint Motion to Dismiss First Amended Complaint ("Joint Brief").

between the alleged harm and Manufacturers' conduct. It also ignores that causation cannot be established as a matter of law where, as here, a string of separate and intervening acts of non-parties caused the harm. *See Martinez v. Pac. Bell*, 225 Cal. App. 3d 1557, 1566 (1990).

Finally, the City's failure (and inability) to allege any false or misleading statements by the Generic Manufacturers forecloses its claims against them. Because Generic Manufacturers are subject to a duty of "sameness," state law claims (like the City's here) based upon a Generic Manufacturer's failure to disclose risks are preempted. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 613 (2011).

II. ARGUMENT

A. The City's Marketing Enterprise RICO Claim Fails as to Manufacturers

1. The City Does Not Sufficiently Allege Causation

The City must allege facts showing that the alleged misconduct was "the proximate cause" of its injuries. *Holmes*, 503 U.S. at 268. But the City cannot do so where, as here, "[m]ultiple steps … separate the alleged fraud from the asserted injury." *Hemi Group LLC v. City of New York, NY*, 559 U.S. 1, 15 (2010). RICO's proximate cause element requires plaintiffs to show "some ***direct*** relation between the injury asserted and the injurious conduct alleged." *Holmes*, 503 U.S. at 268 (emphasis added). And "[t]he general tendency of the law, in regard to damages at least, is not to go beyond the first step." *Id.* at 271. Here, the City's causal chain goes far beyond "the first step." *Id.* It encompasses, at minimum, the following speculative series of events:

(a) A Manufacturer misrepresented a prescription opioid medication's risks or efficacy;
(b) A prescriber in San Francisco actually was exposed to that misrepresentation;
(c) Instead of exercising independent medical judgment, that prescriber prescribed that Manufacturer's opioid to a San Francisco resident based on that misrepresentation rather than medical training, knowledge, and experience regarding the risks of opioids;
(d) The prescription was medically unnecessary and harmful;
(e) The patient chose to fill that prescription without knowledge of the risks of opioids;
(f) The patient became addicted to opioids as a result of that fraudulently-induced and medically inappropriate prescription, as opposed to other factors;
(g) The patient chose to move from prescription opioids to illegal non-prescription drugs or the medically inappropriate prescription was illegally diverted for illicit use; and
(h) The City incurred public costs to address the misuse, abuse, or addiction of opioids that would not have occurred but for the Manufacturer's misrepresentation.[3]

[3] The MDL court looked past this attenuated chain by artificially collapsing it to three links that

That attenuated chain fails to establish the "direct relation" *Holmes* requires. The Ninth Circuit "applies the following three-factor 'remoteness' test: (1) whether there are more direct victims of the alleged wrongful conduct who can be counted on to vindicate the law as private attorneys general; (2) whether it will be difficult to ascertain the amount of the plaintiff's damages attributable to defendant's wrongful conduct; and (3) whether the courts will have to adopt complicated rules apportioning damages to obviate the risk of multiple recoveries." *Oregon Laborers-Employers Health & Welfare Tr. Fund v. Philip Morris Inc.*, 185 F.3d 957, 963 (9th Cir. 1999) (citing *Holmes*, 503 U.S. at 269–70). Not all factors must be satisfied to defeat causation, *see Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 459 (2006), but here, each is met.

First, both the State of California in a law enforcement capacity and the unidentified individuals whose injuries allegedly created increased public costs to the City, FAC ¶¶ 851(b)–(f), 882(b)–(f), are "more direct victims … who can be counted on to vindicate the law." *Oregon Laborers*, 185 F.3d at 963. Second, "ascertain[ing] the amount of the [City]'s damages attributable to [Manufacturers'] wrongful conduct," *id.*, as opposed to "numerous alternative causes that might be the actual source," *Canyon Cnty*, 519 F.3d at 983, would not be merely be "difficult"—it would require "dizzying complexity and … rank-guess work [sic]," *City of New Haven v. Purdue Pharma, L.P.*, 2019 WL 423990, at *4 (Conn. Super. Ct. Jan. 8, 2019) (dismissing municipal claims against manufacturers of opioid medications under *Holmes*). There are numerous equally plausible "alternative causes" of decreased funding for public services and increased public expenditures related to opioids, such as "changes in public health practices," "alterations in criminal laws or policy," and drug trafficking. *Canyon Cnty.*, 519 F.3d at 983. These alternative causes' independence from Manufacturers' marketing forecloses the City's marketing RICO claim. *See In re Bextra & Celebrex*, 2012 WL 3154957, at *6-8 (N.D. Cal. Aug. 2, 2012) (Breyer, J.).

Finally, allowing suits like this one to proceed under RICO would necessitate "complicated rules apportioning damages to obviate the risk of multiple recoveries," *Oregon Laborers*, 185 F.3d at 963, by thousands of governments, businesses, and other entities indirectly injured by the opioid

---

ignore necessary actors in the chain like prescribers and opioid abusers. *See In re Nat'l Prescription Opiate Litig.*, 2018 WL 6628898, at *5 (N.D. Ohio Dec. 19, 2018). That analysis fails to follow the rigorous causation of *Holmes* and the Ninth Circuit precedent applying it.

abuse crisis, *see City of New Haven*, 2019 WL 423990, at *5 ("So [the State and private individuals] are … better situated to sue than the cities suing here. And thus the third *Holmes* factor, and thus all the factors, require this court to dismiss the cities' claims."). The Supreme Court's "precedents make clear that in the RICO context, the focus is on the directness of the relationship between the conduct and the harm." *Hemi Group*, 559 U.S. at 15. That bedrock rule precludes RICO liability for the diffuse downstream injuries the City asserts.[4]

2. The City Fails to Allege Any Marketing Predicate Act with Particularity

The City's RICO Marketing Enterprise claim is based entirely on allegations of mail and wire fraud—that certain Manufacturers fraudulently marketed opioids in San Francisco. *See, e.g.*, FAC ¶¶ 766, 777, 779, 792, 828, 841. But despite the applicability of Rule 9(b), the City has not alleged "the time, place, and specific content of the false representations as well as the identities of the parties" as to ***any*** Manufacturers' alleged misrepresentation ***in San Francisco***. *Sanford v. MemberWorks, Inc.*, 625 F.3d 550, 558 (9th Cir. 2010) (affirming dismissal of RICO claims under Rule 9(b) for failure to plead such details for mail and wire fraud claims). Indeed, it has not even identified any specific wire transactions or uses of the mail to support its claim. The Complaint is also riddled with group pleading, *see, e.g.,* FAC ¶¶ 8-11, 25-28, that improperly "lump[s] multiple defendants together" without "inform[ing] each defendant separately of the allegations surrounding his alleged participation in the fraud." *Swartz v. KPMG LLP*, 476 F.3d 756, 764–65 (9th Cir. 2007) (internal quotations omitted). As discussed *infra* at Parts II.C.2 and II.C.3, the City's allegations are also insufficient to plead any actionable misrepresentation or to attribute any false third-party statements to Manufacturers. For all these reasons, Plaintiff fails to plead RICO predicate acts.

B. The City's Supply Chain Enterprise RICO Claim Fails as to Manufacturers[5]

1. The City Does Not Sufficiently Allege Causation

[4] The City here is further removed from the third-party payors in *Painters & Allied Trades District Council 82 Health Care Fund v. Takeda Pharmaceuticals Co. Ltd.*, 943 F.3d 1243, 1247 (9th Cir. 2019). There, third-party payors sued a pharmaceutical company that had allegedly defrauded them into reimbursing its medications. Those indirect injuries pushed RICO causation to its limits, as the decision made clear by detailing a circuit split about their viability. *See id.* at 1252-59. The City does not seek recovery for prescriptions it paid for, but rather for downstream municipal costs contingent on third-party behavior, harm and illegal conduct, which is dramatically more remote.

[5] The City does not bring this claim against Noramco, Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., or Janssen Pharmaceutica, Inc. FAC ¶ 797.

At the heart of the City's Supply Chain Enterprise claims is its theory that the Manufacturers' purported failure to monitor and report suspicious orders of prescription opioid medications to the DEA caused public expenditures associated with prescription opioid misuse, abuse, and addiction. FAC ¶ 882. But the City's chain of causation assumes (but does not plead) that: (i) the Manufacturers shipped orders to distributors in violation of their duties to monitor, report, and stop shipment of "suspicious orders"; (ii) those distributors violated their own obligations and instead distributed the orders to pharmacies in San Francisco; (iii) those pharmacies likewise ignored their legal obligations and disbursed those suspicious orders to patients; (iv) those patients misused, abused, and/or diverted those prescription opioid medications for illicit use or chose to move from prescription opioids to illegal non-prescription drugs; (v) those patients or other San Francisco residents were physically harmed as a result of those prescription opioid medications or that diversion; and (vi) the City suffered economic injuries as a result. Under *Canyon County*, the alleged harm is too remote from the alleged conduct and proximate cause is absent. 519 F.3d at 982-83.

Nor can the City establish but-for-causation. The FAC does not identify a single "suspicious" order from San Francisco that a Manufacturer should have reported or stopped. Nor does the FAC suggest that had the Manufacturers reported these unidentified orders to the DEA then the DEA would have taken action to avert prescription opioid diversion and related societal harms in San Francisco, thereby avoiding the City's alleged resultant public expenditures. The City pleads no facts to support its vague, conclusory, and speculative allegation that Manufacturers' failure to report suspicious orders led to the "oversupply of opioids to San Franciscans." FAC ¶ 915; *see Canyon Cnty.*, 519 F.3d at 983-84 ("speculative … causal links" insufficient to state a RICO claim).

2. The City Does Not Allege Any Predicate Act with Particularity

The City purports to base its Supply Chain Enterprise claim on three predicate fraud activities: (1) mail fraud, (2) wire fraud, and (3) furnishing false or fraudulent information in documents filed with the DEA. FAC ¶¶ 797–825. But the City's allegations fail to identify (let alone describe with particularity) even ***one*** fraudulent statement or omission regarding Manufacturers' diversion monitoring obligations or even ***one*** "suspicious" order affecting San Francisco. Nor does the City identify what false information any Manufacturer allegedly submitted to the DEA,

when it did so, what was said, or how it was linked to any prescription in San Francisco. The City's Supply Chain Enterprise claim therefore fails. *See Sanford*, 625 F.3d at 558.

C. The FAC Fails To State a Claim Under the False Advertising Law and Fraudulent Business Practices Prong of The Unfair Competition Law

The City claims that Manufacturers promoted opioids as safe and effective for chronic pain while minimizing or concealing opioids' risks. But that claim fails, for at least three reasons.

1. The Claims Are Barred Under California's Safe Harbor Doctrine

California's safe-harbor doctrine forecloses FAL and UCL claims if "another provision" of law "'bar[s]' the action or clearly permit[s] the conduct" at issue. *Cel-Tech*, 20 Cal. 4th at 183. In cases concerning FDA-regulated prescription medications, courts have applied the doctrine to dismiss FAL and UCL claims that a drug's FDA-approved label misrepresented its efficacy. *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 2014 WL 866571, at *4 (D. Mass. Mar. 5, 2014) (holding California's "safe harbor provision applies to bar a claim that the [FDA-approved] label was false or misleading").[6] Importantly, safe-harbor doctrines bar not only claims regarding a drug's FDA-approved labeling, but also *advertisements* and *promotions* that "generally comport" therewith. *Prohias v. Pfizer, Inc.*, 490 F. Supp. 2d 1228, 1235 (S.D. Fla. 2007).[7]

The safe-harbor doctrine defeats the City's marketing-based FAL and UCL claims, which, at their core, attack one thing: Manufacturers' allegedly "false position that opioids were safe and effective for treatment of chronic pain." FAC ¶ 453. As explained in the Joint Brief, by approving Manufacturers' prescription opioid medications for long-term treatment of chronic pain, the FDA determined they are safe and effective when properly prescribed and used for such treatment. *See* Joint Br. at 27-28. Similarly, recognizing that "[i]nadequate treatment of ... chronic pain originating from cancer *or noncancerous conditions* is a significant health problem," California law ensures that "[a] patient who suffers from severe chronic intractable pain has the option to request" any "opiate medications," Cal. Health & Safety Code § 124960 (emphasis added), and that physicians

[6] *See also Ebner v. Fresh Inc.*, 2013 WL 9760035, at *6 (C.D. Cal. Sept. 11, 2013); *POM Wonderful LLC v. Coca–Cola Co.*, 2013 WL 543361, at *5 (C.D. Cal. Feb. 13, 2013).

[7] *See also Newman by Newman v. McNeil Consumer Healthcare*, 2013 WL 7217197, at *5 (N.D. Ill. Mar. 29, 2013); *DePriest v. AstraZeneca Pharm., L.P.*, 2009 Ark. 547, 16, 19 (2009); *Cytyc Corp. v. Neuromedical Sys., Inc.*, 12 F. Supp. 2d 296, 301 (S.D.N.Y. 1998).

"may prescribe a dosage [of opiate therapy] deemed medically necessary to relieve the patient's pain." *Id.* § 124961. Given the FDA's approval and California law protecting the use of Manufacturers' opioids for long-term pain, the City's claims under the FAL and UCL fail.

2. The Statements at Issue Are Not Likely to Mislead Reasonable California Prescribers and Are Not Otherwise Actionable

a. The At-Issue Statements Are Not Likely to Deceive Given Opioid Labeling's Disclosure of Potential Risks

Nearly all of the City's eight[8] alleged "falsehoods" reflect its theory that Manufacturers and third parties did not sufficiently "disclose in promotional materials the risks of addiction, overdose, and death." *See* FAC ¶¶ 228(a)-(e), (g), (i); 337.[9] But these alleged "falsehoods" are not actionable under the FAL and UCL unless they were "likely to deceive ... a significant portion of … targeted consumers, acting reasonably in the circumstances." *Lavie*, 105 Cal. App. 4th at 504, 507-08, 512; *see In re Vioxx Class Cases*, 180 Cal. App. 4th 116, 130 (2009). In making that determination, courts do not consider a challenged statement in isolation; instead, courts must consider the relevant circumstances, including "the knowledge base" of the targeted consumer, *Patricia A. Murray Dental Corp. v. Dentsply Int'l, Inc.*, 19 Cal. App. 5th 258, 272 (2018), and other disclosures that bear on the at-issue statement's allegedly deceptive nature, *see Freeman v. Time, Inc.*, 68 F.3d 285, 290 (9th Cir. 1995) (affirming dismissal of FAL and UCL claims where "[a]ny ambiguity that [plaintiff] would read into any particular statement [was] dispelled by the promotion as a whole").[10] These principles defeat the City's FAL and UCL claims because Manufacturers' labels and branded promotions detailed the allegedly concealed or misrepresented risks.

Product labeling "is the cornerstone of risk minimization efforts for most of the drugs approved by the FDA" and the primary means of conveying those risks to prescribing physicians. *See*

[8] The FAC alleges a ninth "falsehood" regarding OxyContin's 12-hour duration, which on its face does not apply to any Manufacturer other than Purdue. *See* FAC ¶¶ 346-358.

[9] To the extent the City alleges off-label promotion, FAC ¶¶ 46, 737-41, prescribers have discretion to prescribe medicines off-label and off-label promotion is not inherently "false or misleading." *United States v. Caronia*, 703 F.3d 149, 165 (2d Cir. 2012); *see also Travelers Indem. Co. v. Cephalon, Inc.*, 32 F. Supp. 3d 538 (E.D. Pa. 2014), *aff'd*, 620 F. App'x 82 (3d Cir. 2015) (dismissing off-label promotion claims identical to those alleged here).

[10] *See also In re Sony Gaming Networks & Customer Data Sec. Breach Litig.*, 996 F. Supp. 2d 942, 990 (S.D. Cal. 2014) (dismissing FAL and UCL claims where defendant's website directed consumers to clarifying material).

Ex. 10 at 19. Physicians in turn have the "duty to transmit these warnings to the patient," *Brown v. Sup. Ct.*, 44 Cal. 3d 1049, 1062 (1988), who can *only* obtain Manufacturers' highly regulated products from physicians authorized to prescribe controlled substances, *see* 21 C.F.R. §§ 1306.11; 1306.03(a)(1). As the only consumers to whom "the duty to warn runs," *see Carlin v. Sup. Ct.*, 13 Cal. 4th 1104, 1116, 1118 (1996), physicians prescribing opioid medications are the "targeted consumer" and are presumed as a matter of law to have within their "knowledge base" the warnings on those opioids' labeling, *Dentsply*, 19 Cal. App. 5th at 272; *Carmichael v. Reitz*, 17 Cal. App. 3d 958, 991 (1971) ("If an adequate warning is received by the person to whom the law requires that the warning be given, the manufacturer may assume that it will be read and heeded.").

While the wording of the FDA-approved labels for the opioid medications at issue has changed over time, they have always detailed the risks of death, addiction, and abuse, including in prominent "black box" warnings. For example, Duragesic's black box warning describes its "risks of addiction, abuse and misuse, which can lead to overdose and death." Ex. 1 at 1; *see* Exs. 2-8 (same). After further detailing opioids' risks—including in Patient Medication Guides—the labeling emphasizes the need for prescribers to counsel and monitor patients for proper use. *See, e.g.*, Ex. 1 at 44-50. Finally, FDA regulations require that all product-specific promotional materials include the risk information provided in the labeling. *See* 21 C.F.R. § 202.1(e)(5).

Against this backdrop, the City's central allegation that Manufacturers violated the FAL and UCL "by downplaying the substantial risks of opioids" and "failing to disclose in promotional materials the risks of addiction, overdose, and death," FAC ¶¶ 27, 337, fails because the risk of addiction and abuse was within the "knowledge base" of and readily available to the "targeted consumer," *i.e.*, prescribing physicians. *See Dentsply*, 19 Cal. App. 5th at 272.

b. The City's Substantiation- and Omission-Based Claims Are Not Cognizable Under the FAL or UCL

The City's allegations that a "lack of evidence" or "lack of data" supported various challenged statements, *see, e.g.*, FAC ¶¶ 319, 321, 332, 372, 380, 700, are inadequate for another reason: Unless a complaint alleging lack of substantiation also provides a "specified factual basis … that [d]efendants' representations … are false, [FAL and UCL] claims fail as a matter of law."

Route v. Mead Johnson Nutrition Co., 2013 WL 658251, at *5 (C.D. Cal. Feb. 21, 2013); *see Fraker v. Bayer Corp.*, 2009 WL 5865687, at *8 (E.D. Cal. Oct. 6, 2009). The FAC fails to do so.

For example, the FAC alleges that "[t]he Marketing Defendants' claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence." FAC ¶ 332. Unable to allege facts capable of proving Manufacturers' challenged statements are actually false, the City cites FDA warning letters to *non-party* opioid manufacturers, the CDC Guideline's statement that "benefits for … function … are *uncertain*," and a handful of articles purportedly showing that long-term opioid use "*may* actually worsen pain and functioning." FAC ¶ 332-35 (emphases added). But none of the cited statements or studies concerns Manufacturers' specific products, let alone purports to disprove any specific claim. Given this "mismatch between the representations at issue and the evidence that allegedly debunks them," the City's claim fails. *Eckler v. Wal-Mart Stores, Inc.*, 2012 WL 5382218, at *1, *7 (S.D. Cal. Nov. 1, 2012); *Engel v. Novex Biotech LLC*, 2014 WL 5794608, at *3-4 (N.D. Cal. Nov. 6, 2014) (dismissing complaint where cited authorities did not refer to the product at issue); *Kwan v. SanMedica Int'l, LLC*, 2014 WL 5494681, at *3-4 (N.D. Cal. Oct. 30, 2014) (same); *Route*, 2013 WL 658251, at *5 (dismissing complaint where cited study discussed evidence supporting and contradicting claims).

The City's claims also fail to the extent they are based on Manufacturers' alleged *omission* of opioids' risks. "[T]o state a claim of fraudulent omissions under the UCL/FAL …, a plaintiff must allege facts either showing that the alleged omissions are 'contrary to a representation actually made by the defendant, or showing an omission of a fact the defendant was obliged to disclose.'" *Andren v. Alere, Inc.*, 207 F. Supp. 3d 1133, 1141 (S.D. Cal. 2016) (citations omitted); *see Buller v. Sutter Health*, 160 Cal. App. 4th 981, 988 (2008). The FAC repeatedly challenges unbranded promotional materials that allegedly encouraged opioid therapy for chronic pain by omitting or "failing to disclose … the risks of addiction, overdose, and death." FAC ¶ 337; *see also id.* ¶¶ 262, 305-06, 307, 336, 339, 427, 484. But the law imposes no duty to include detailed risk information in such materials: while FDA's regulations require a summary of that information in *product-specific* advertising and promotion, those regulations do *not* apply to non-product-specific materials. *See* 21 U.S.C. § 352(n); 21 C.F.R. § 202.1(e)(5)(ii). Given the absence of any legal duty to disclose

them, and their consistency with FDA-approved labels, the alleged omissions do not support the City's FAL and UCL claims.

3. Third-Party Statements Are Not Actionable Because They Are Neither Commercial Nor Legally Attributable to Manufacturers

The City's reliance on third parties' statements cannot support its FAL and UCL claims because the FAC does not allege Manufacturers' "personal 'participation in the unlawful practices' and 'unbridled control' over" those third parties' challenged acts. *Emery*, 95 Cal. App. 4th at 960 (citation omitted); *see also Perfect 10, Inc. v. Visa Serv. Int'l Ass'n*, 494 F.3d 788, 808-09 (9th Cir. 2007). Nor do the City's allegations support its bare assertion that "the actions described in" the FAC were done with "Defendants' actual, apparent, and/or ostensible authority." FAC ¶ 174.

The FAC uses suggestive labels like "front groups" and relies on vague and conclusory allegations that Manufacturers "exerted influence and effective control over the messaging by these groups by providing major funding … to them," *id.* ¶ 403, and "took an active role in guiding, reviewing, and approving" these groups' messaging, *id.* ¶ 407; *see also id.* ¶¶ 227, 410, 413, 414, 450, 451, 459, 783, 784. But allegations of funding and generic oversight do not show the requisite "personal participation" in and "unbridled control" over specifically challenged third-party statements, let alone an agency relationship. *Emery*, 95 Cal. App. 4th at 960; *see Gen. Bldg. Contractors Ass'n, Inc. v. Pennsylvania*, 458 U.S. 375, 395 (1982) ("fund[ing] the activities of [an organization] does not render [it] [a defendant's] servant or agent …."); *Batzel v. Smith*, 333 F.3d 1018, 1036 (9th Cir. 2003) (providing "financial support does not support an inference that [defendant] possessed practical control of [the recipient's] editorial content").

Furthermore, many of the challenged third-party statements constitute non-commercial speech "beyond the[] reach" of the FAL or UCL. *Critical Care Diagnostics, Inc. v. Am. Ass'n for Clinical Chem., Inc.*, 2014 WL 634206, at *8 (S.D. Cal. Feb. 18, 2014). Most of the third parties at issue here—medical societies, patient advocacy groups, *e.g.*, FAC ¶¶ 272, 305, 323, 326, 339, and doctors and individuals speaking about their experience with opioids, *id.* ¶¶ 300, 327, 411—are not commercial speakers because they do not "manufacture, import, distribute, and sell" opioids or

speak on behalf of anyone that does, and their public statements, scientific articles, treatment guidelines, and CME materials are not commercial in character; instead, they all address scientific and medical matters of public interest on which their authors have the constitutional right to speak. *Bernardo*, 115 Cal. App. 4th at 344-48 (Planned Parenthood "fact sheets" that were "educational in nature" and concerned "disputed scientific and medical issues of public interest" were non-actionable); *Critical Care*, 2014 WL 634206, at *8 (scientific research article non-actionable); *Stutzman v. Armstrong*, 2013 WL 4853333, at *15 (E.D. Cal. Sept. 10, 2013) (books containing individual's account of his experiences were not actionable). That the City disagrees with this protected speech cannot turn it into a violation of the FAL or UCL.

D. The FAC Fails to State a Claim Under the UCL's Unlawful Prong

As the UCL's "unlawful prong" "borrows violations of other laws," *Randall v. Ditech Fin., LLC*, 23 Cal. App. 5th 804, 811 (2018), failing to plead the predicate claim with reasonable particularity means the "UCL claim also fails," *Aleksick*, 205 Cal. App. 4th at 1185; *Khoury v. Maly's of Cal., Inc.*, 14 Cal. App. 3d 1013, 1016 (1986). The City does not adequately allege violations of RICO or the FAL, *supra* at 2-11; Joint Br. at 6-12, so neither can support its UCL claim. Likewise, the City fails to plead a predicate CLRA violation and thus fails to state any UCL "unlawful" claim.

To maintain a CLRA action, a plaintiff must plead facts showing that (1) the defendant committed one or more proscribed practices, (2) California consumers suffered an injury, and (3) the injury was a result of the proscribed conduct. Cal. Civ. Code § 1780(a); *Meyer v. Sprint Spectrum L.P.*, 45 Cal. 4th 634, 641 (2009). The City fails to do so.

First, while the FAC is unclear, it appears the City intended to invoke Sections 1770(a)(5) and (8) by alleging that each Manufacturer "represented that its prescription opioids and/or prescription opioids in general had characteristics, uses and benefits that they did not have and disparaged other medications, including NSAIDs, by false and misleading representations of fact." FAC ¶ 911. This is insufficient to state a CLRA claim. For Section 1770(a)(5), the safe harbor doctrine discussed above bars claims about the "characteristics, uses and benefits" of Manufacturers' products for long-term treatment of chronic pain. *See supra* at 6-7. For Section 1770(a)(8), the FAC

cites only general information about pain treatments, FAC ¶¶ 338-44, rather than, as required, identifying "by express mention or by clear implication" a "false or misleading statement that (1) specifically refers to [a specific competitor]'s product … and (2) clearly derogates that product." *Hartford Cas. Ins. Co. v. Swift Distrib., Inc.*, 59 Cal. 4th 277, 284 (2014).

Second, the City fails to adequately allege injury to specific San Francisco consumers "who suffer[ed] damage." *Durell v. Sharp Healthcare*, 183 Cal. App. 4th 1350, 1367 (2010). While the City alleges harm associated with "opioids" generally, *e.g.*, FAC ¶¶ 14, 918, it fails to allege particularized facts about specific patients prescribed and harmed by Manufacturers' opioids.

Third, while the City asserts that "[Manufacturers]' marketing activities were successful in driving the sale of [their] opioids in San Francisco" and that they "caused substantial injury," FAC ¶¶ 40, 918, bare allegations like these are not sufficient to support a causal link between Defendants' alleged CLRA violations and consumers' alleged harm. As explained *supra* at Part II.A.1, multiple significant and independent intervening events foreclose the City's unpled assumption that Manufacturers' promotions proximately caused *specific* doctors to prescribe Manufacturers' *specific* products to *specific* patients, who were then harmed by proper use of those products. *See In re Actimmune Mktg. Litig.*, 2009 WL 3740648, at *16 (N.D. Cal. Nov. 6, 2009) (dismissing CLRA claim for failure to allege causal link); *Brownfield v. Bayer Corp.*, 2009 WL 1953035, at *4 (E.D. Cal. July 9, 2009) (dismissing CLRA claim where plaintiffs "fail[ed] to adequately allege a connection between [their] injury, if any, and the complained-of conduct of [defendant's] Ads").

E. The FAC Fails to State a Claim Under the UCL's Unfair Prong

The City's claims fail under the UCL's "unfair" prong for the reasons explained in the Joint Brief. Joint Br. at [21]. Under the balancing test endorsed by the Ninth Circuit, *Lozano v. AT & T Wireless Servs., Inc.*, 504 F.3d 718, 735–36 (9th. Cir. 2007), Manufacturers had a "strong justification" for providing the opiate therapy to pain patients that California law protects, *Davis*, 691 F.3d at 1170; *supra* at 1-2, and the City fails to adequately allege harm to a single San Franciscan caused by Manufacturers' marketing, *supra* at 6.

F. The City Fails to Plead Facts Sufficient to Establish That Manufacturers' Conduct Caused the Alleged Nuisance

As discussed in the Joint Brief, a plaintiff in a public nuisance action must plead and prove but-for and proximate causation. Joint Br. at 23-24. The FAC fails to do so. The City alleges in conclusory fashion that "[t]he unlawful conduct of each of the Defendants was a substantial factor in producing harm to the People …." FAC ¶ 903. That legal conclusion is not supported by any well-pled *facts* establishing the "causal connection" between the Manufacturers' conduct and the alleged nuisance. *See In re Firearm Cases*, 126 Cal. App. 4th 959, 967 (2005). For example, the City seeks to hold Manufacturers responsible for a host of social ills relating to opioid abuse and misuse, including "San Franciscans … shooting up on the street," drug trafficking, San Francisco "library staff [getting] stuck by needles in the [library] stacks," "frequent 911 call[s]," and "fentanyl being sent into the jails." FAC ¶¶ 55-57. Each of these social ills, however, is just as plausibly the result of myriad intervening acts—including the decision-making of prescribers, patients, distributors, pharmacies, and third-party criminals never even prescribed an opioid medication—which defeats its public nuisance claim. *See Martinez*, 225 Cal. App. 3d at 1566 (dismissing nuisance claim where "a separate and intervening act" caused the harm).

In re Firearm Cases is instructive. There, the Court of Appeal affirmed summary judgment in favor of defendants, who were alleged to have "marketed handguns using practices that encourage sales to unauthorized users without adequately monitoring their distributors and dealers …." 126 Cal. App. 4th at 973. The court rejected plaintiffs' public-nuisance claim and found no "causal connection between any conduct of the defendants and any incident of illegal acquisition of firearms or criminal acts or accidental injury by a firearm." *Id.* at 989. The court also warned against the view of public-nuisance law advanced by the City here: absent limitations, "[a]ny manufacturer of an arguably dangerous product … can be hauled into court in California to defend against a civil action brought by a victim of the criminal use of that product." *Id.* at 991 (citation omitted). The City's public-nuisance claim depends on a causal theory even more attenuated than that advanced in *In re Firearms*, as it seeks to hold Manufacturers liable for the criminal use of products they never even manufactured or distributed (*e.g.*, street heroin and fentanyl smuggled from overseas), as well as for attendant social ills. The claim should be dismissed.

G. The Marketing Claims Against Generic Manufacturers Are Preempted

The marketing claims against Manufacturers rest on the theory that they falsely promoted prescription opioid medications. But Generic Manufacturers manufacture or sell generic medicines and do not promote their safety and efficacy. They "compete on price and avoid marketing to physicians because the costs of such marketing severely impact their ability to offer the significantly lower prices upon which they compete." *New York v. Actavis, PLC*, 2014 WL 7015198, at *27 (S.D.N.Y. Dec. 11, 2014). Any purported false promotion by a Generic Manufacturer would require an implausible departure from industry norms because (1) the manufacturer would incur the cost of promotion, even though doctors do not prescribe specific to that manufacturer, and (2) the manufacturer would incur further costs of non-identical marketing, inconsistent with Generic Manufacturers' governing "sameness" regime that is designed to lower costs in the first place.

For this reason, the City failed to make a ***single particularized allegation*** as to any Generic Manufacturer's marketing generally, much less one describing (with particularity or otherwise) a false statement attributable to any Generic Manufacturer that reached (let alone influenced) any San Francisco prescriber. Because of this failure, the City does not, and cannot, plead that Generic Manufacturers' unpled statements caused any of the City's alleged injuries. Absent allegations that Generic Manufacturers affirmatively promoted the safety and efficacy of their generic medicines—indeed, they did not[11]—the City's marketing claims necessarily rest upon a failure to warn theory, *i.e.*, that Generic Manufacturers did not sufficiently disclose the risks of using opioids. FAC ¶¶ 80, 303, 307, 337, 521, 769, 892, 911, 923. But such claims are preempted.

As the Supreme Court explained in *Mensing*, generic medicines have a duty of "sameness" and must always adhere to their reference list medication.[12] This duty extends beyond product labels to promotional and advertising materials.[13] After FDA approval, while brand manufac-

[11] Judge Polster found otherwise, but he did so based on the "Sixth Circuit['s] relaxed [group] pleading standards." *In Re: Nat'l Prescription Opiate Litig.*, 1:17-md-2804, ECF No. 1680, at 3. But the Ninth Circuit holds that "Rule 9(b) does not allow a complaint to merely lump multiple defendants together …." *Swartz v. KPMG LLP*, 476 F.3d 756, 764–65 (9th Cir. 2007).

[12] The FDCA imposes different requirements on manufacturers of brand medicines versus generic medicines. *Mensing*, 564 U.S. at 612.

[13] "Labeling" means "all labels and other written, printed, or graphic matter (1) upon any article

turers may revise their labeling without prior FDA approval to add or strengthen a "contraindication, warning, [or] precaution," 21 C.F.R. § 314.70(c)(6)(iii)(A), generic manufacturers can change their labeling only "to match an updated brand-name label or to follow the FDA's instructions," *Mensing*, 564 U.S. at 614. Outside those circumstances, "changes unilaterally made to strengthen a generic drug's warning label would violate the statutes and regulations requiring a generic drug's label to match its brand-name counterpart's." *Id.* Thus, state-law claims that would require additional or different warnings for generic medicines are preempted, since generic manufacturers cannot simultaneously comply with state law requirements and their federal law duty of sameness.[14] *Id.* at 618; *see Mut. Pharm. Co., Inc. v. Bartlett,* 570 U.S. 472, 486-487, 490 (2013) (state law claims questioning adequacy of generic drug labeling preempted under *Mensing*).

As in *Mensing*, the City's FAC, UCL, and public nuisance claims are preempted because they would require the Generic Manufacturers to change their labels or otherwise provide different safety warnings, which they cannot do.[15] The City cannot avoid preemption by arguing that the Generic Manufacturers should have communicated risks about prescription opioid medications to counteract allegedly false promotion by others in the marketplace, since generic manufacturers are not permitted to communicate *any warnings* beyond a generic label if brand-name manufacturers have not already sent such a communication. *See Mensing*, 564 U.S. at 615.[16]

III. CONCLUSION

For the foregoing reasons, Manufacturers request that the Court dismiss the FAC.

---

or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m); *see also* 21 C.F.R. § 202.1(1)(2) (adopting definition of "labeling" that includes "detailing pieces").

[14] This analysis also applies to the RICO claims, since preemption principles are "instructive" as to "the alleged preclusion of a cause of action under one federal statute" (RICO) "by the provisions of another" (FDCA). *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 111 (2014).

[15] *See In re Darvocet, Darvon, and Propoxyphene Prods. Liability Litig.,* 756 F.3d 917, 935–36 (6th Cir. 2014); *Bell v. Pfizer, Inc.*, 716 F.3d 1087, 1095 (8th Cir. 2013); *see also Moretti v. Wyeth, Inc.*, 579 F. App'x 563, 566 (9th Cir. 2014).

[16] The MDL Court recognized that any failure to disclose claims are preempted under controlling law. *See The Muscogee (Creek) Nation v. Purdue Pharma L.P., et al*, 1:18-op-45459, ECF. No. 104 at 42, Report and Recommendation.

Dated: April 17, 2020

/s/ *Amy R.. Lucas*

Amy R. Lucas (S.B. #264034)
O'MELVENY & MYERS LLP
1999 Avenue of the Stars, 8th Floor
Los Angeles, CA 90067
Tel: (310) 553-6700
Fax: (310) 246-6779
alucas@omm.com

Charles C. Lifland (S.B. #108950)
Sabrina H. Strong (S.B. #200292)
O'MELVENY & MYERS LLP
400 South Hope Street
Los Angeles, CA 90071
Tel: (213) 430-6000
Fax: (213) 430-6407
clifland@omm.com
sstrong@omm.com

Amy J. Laurendeau (S.B. #198321)
O'MELVENY & MYERS LLP
610 Newport Center Drive, 17th Floor
Newport Beach, CA 92660
Tel: (949) 823-6900
Fax: (949) 823-6994
alaurendeau@omm.com

Stephen D. Brody (*pro hac vice*)
O'MELVENY & MYERS LLP
1625 Eye Street, NW
Washington, DC 20006
Tel: (202) 383-5300
Fax: (202) 383-5414
sbrody@omm.com

Attorneys for Defendants Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica, Inc.

/s/ *Wendy West Feinstein*
Zachary Hill (S.B. #275886)
MORGAN, LEWIS & BOCKIUS LLP
One Market, Spear Street Tower
San Francisco, CA 94105-1596
Tel: (415) 442-1000
Fax: (415) 442-1001
zachary.hill@morganlewis.com

Wendy West Feinstein (*pro hac vice*)
MORGAN, LEWIS & BOCKIUS LLP
One Oxford Centre, Thirty-Second Floor
Pittsburgh, PA 15219-6401
Tel: (412) 560-7455
Fax: (412) 560-7001
wendy.feinstein@morganlewis.com

Attorneys for Defendants Teva Pharmaceuticals USA, Inc.; Cephalon, Inc.; Actavis LLC; Actavis Pharma, Inc. f/k/a Watson Pharma, Inc; Watson Laboratories, Inc.; Warner Chilcott Company LLC; Actavis South Atlantic LLC; Actavis Elizabeth LLC; Actavis Mid Atlantic LLC; Actavis Totowa LLC; Actavis Kadian LLC; Actavis Laboratories UT, Inc. f/k/a Watson Laboratories, Inc.-Salt Lake City; and Actavis Laboratories FL, Inc. f/k/ Watson Laboratories, Inc.-Florida.

/s/ *Sean O. Morris*
Sean O. Morris
John D. Lombardo
ARNOLD & PORTER KAYE SCHOLER LLP
777 South Figueroa Street, 44th Floor
Los Angeles, CA 90017-5844
Tel: +1-213-243-4000
Fax: +1-213-243-4199
Sean.Morris@arnoldporter.com
John.Lombardo@arnoldporter.com

Attorneys for Defendants Endo Pharmaceuticals Inc., Endo Health Solutions Inc., Par Pharmaceutical, Inc., and Par Pharmaceutical Companies, Inc.

/s/ *Rocky C. Tsai*
Rocky C. Tsai (S.B. #221452)
Traci J. Irvin (S.B. #309432)
ROPES & GRAY LLP
Three Embarcadero Center
San Francisco, CA 94111-4006
Tel: (415) 315-6300
Fax: (415) 315-6350
rocky.tsai@ropesgray.com
traci.irvin@ropesgray.com

Attorneys for Defendants Mallinckrodt LLC and SpecGx LLC

/s/ *Karl Stampfl*
Zachary W. Byer (S.B. #301382)
KIRKLAND & ELLIS LLP
555 South Flower Street
Los Angeles, CA 90071
Tel: (213) 680-8400
michael.onufer@kirkland.com

Jennifer G. Levy, P.C. (*pro hac vice*)
KIRKLAND & ELLIS LLP
1301 Pennsylvania Ave., N.W.
Washington, D.C. 20004
Tel: (202) 879-5000
Fax: (202) 879-5200
jennifer.levy@kirkland.com

Donna Welch, P.C. (*pro hac vice*)
Timothy W. Knapp, P.C. (*pro hac vice*)
Karl Stampfl (*pro hac vice*)
KIRKLAND & ELLIS LLP
300 North LaSalle, Chicago, IL 60654
Tel: (312) 862-2000
Fax: (312) 862-2200
donna.welch@kirkland.com
tknapp@kirkland.com
karl stampfl@kirkland.com

Attorneys for Defendants Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a/ Watson Pharmaceuticals, Inc., Allergan Sales, LLC, Allergan USA, Inc. and specially appearing Allergan plc

/s/ *Elizabeth A. Sperling*
Elizabeth A. Sperling (S.B. #231474)
ALSTON & BIRD LLP
333 South Hope Street, 16th Floor
Los Angeles, CA 90071
Tel: (213) 576-1000
Fax: (213) 576-1100
elizabeth.sperling@alston.com

Daniel G. Jarcho (*pro hac vice forthcoming*)
ALSTON & BIRD LLP
950 F Street, NW
Washington, DC 20004
Tel: (202) 239-3300
Daniel.jarcho@alston.com

Cari K. Dawson (*pro hac vice*)
Jenny A. Hergenrother (*pro hac vice forthcoming*)
ALSTON & BIRD LLP
1201 West Peachtree Street, Suite 4900
Atlanta, GA 30309-3424
Tel: (404) 881-7000
cari.dawson@alston.com
jenny.hergenrother@alston.com

Attorneys for Defendant Noramco, Inc.

ATTESTATION

I, Amy R. Lucas, hereby attest, pursuant to N.D. Ca. Civil L.R. 5-1, that the concurrence to the filing of this document has been obtained from each signatory hereto.

DATED: April 17, 2020

/s/ *Amy R. Lucas*
Amy R. Lucas